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10/005,902

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Dale Brown

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BANNER & WITCOFF, LTD.

28 STATE STREET

28th FLOOR

BOSTON, MA 02109-9601

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/005,902 | <b>Applicant(s)</b><br>BROWN ET AL. |  |
|                              | <b>Examiner</b><br>SHIRLEY V. GEMBEH | <b>Art Unit</b><br>1618             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendments and Arguments***

1. The response filed on **6/11/09** has been entered
2. Applicant's arguments filed 6/11/09 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 26-39 are pending in this office action. Claims 15-25 have been cancelled.
5. The information disclosure statement (IDS) submitted on 10/16/08 is acknowledged and has been reviewed.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller (US 5,129,824).

Keller teaches a self-treatment method of treating gingival comprising: physically removing biofilm from the tooth surface (i.e., supra gingival) with a tooth brush (see abstract, as required by item 26a which reasonably include toothpaste with soft abrasives), which also reasonably removes biofilm from the interproximal tooth surface (between the teeth) (as required by item 26b and 27-28). Inherently a toothbrush includes three to five ribs and grooves (as required by instant claims 30-33). Keller also teaches that dental floss is employed to remove biofilm from subgingival surfaces (as required by item 26c and 29) wherein the gingival detachment is about 3mm (see col. 7, lines 45-47). Keller further teaches the use of dental floss for applying medicament to the infected site (see col. 5, lines 1-14) which inherently will remove biofilm from the tooth surface because Keller teaches "the teeth are flossed in the usual manner".

Additionally Keller teaches the use of gel (i.e., proxy gel/tooth paste inherently comprises soft abrasives; as required by instant claim 28; see abstract and col. 3, lines 23-25) wherein reasonably the gel contains soft abrasives for brushing the teeth.

7. Claims 26-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller (US 5,129,824) in view of Hill (US 5,993,784) and Aberg et al. (US 5,807,541).

Applicant argues that the "self treatment method" taught by Kelly "is in fact something beyond the ability of ordinary people to perform" and further traverses that "[w]hile flossing and brushing are both "self administration" techniques, injection of a medicament such as tetracycline into various areas of gum tissue in the mouth (upper,

lower, inside and outside, front and back) - by the person having gingival detachment - is neither routine nor ordinary self-treatment - regardless of what the Keller patent claims”.

Applicant traverses that Keller only teaches the delivery of microbial or antibiotics to the area and nothing more, and none of Keller’s techniques deliver soft abrasives for physical or mechanical removal biofilms from the three tooth surfaces claimed in the instant application.

Additionally, Applicant argues that “Hill only provides tooth brush with 3-5 grooves, and uses that with toothpaste with soft abrasives arguing that the use of Hill’s toothpaste will likely interfere with Keller’s medicine and lastly, Applicant argued that nothing in Aberg teaches or suggest the physical/mechanical removal of biofilm”.

In response Applicants’ claimed invention is directed to a self-treatment method, and Keller’s teaching is a self-treatment method. Whether it’s possible for a person administer “injection of a medicament such as tetracycline into various areas of gum tissue in the mouth (upper, lower, inside and outside, front and back) - by the person having gingival detachment - is neither routine nor ordinary self-treatment - regardless of what the Keller patent claims” is an embodiment that is not claimed by the instant application. Applicant further fails to realize that this is a rejection under 35 USC 103 and not 102. Keller teaches active agents may be added to the self-treatment method, and gives examples such as antibiotics. Therefore one of ordinary skill in the art, based on the type of disease of the gum to be treated, would be motivated to substitute other

agents such as NSAID's to the self-treatment method of Keller, especially for the treatment of inflammation of the gum which is reasonably associated with gum diseases.

In summary the rejection has been rewritten to address the new claims submitted. Nonetheless, the scope of the rejection remains the same, as before.

Keller teaches a self-treatment method of treating gingival comprising: physically removing biofilm from the tooth surface (i.e., supra gingival) with a tooth brush (see abstract, as required by item 26a which reasonably includes toothpaste with soft abrasives), which also reasonably removes biofilm from the interproximal tooth surface (between the teeth) (as required by item 26b and 27-28). Inherently a toothbrush includes three to five ribs and grooves (as required by instant claims 30-33). Keller also teaches that dental floss is employed to remove biofilm from subgingival surfaces (as required by item 26c and 29) wherein the gingival detachment is about 3mm (see col. 7, lines 45-47). Keller further teaches the use of dental floss for applying medicament to the infected site (see col. 5, lines 1-14) which inherently will remove biofilm from the tooth surface because Keller teaches "the teeth are flossed in the usual manner".

Additionally Keller teaches the use of gel (i.e., proxy gel/tooth paste which inherently comprises soft abrasives; as required by instant claim 28, see abstract and col. 3, lines 23-25) wherein reasonably the gel contains soft abrasives for brushing the teeth.

However Keller fails to teach using ribbed and grooved bristled tooth brushes, or use of therapeutic agents such as NSAIDs (i.e., as it relates to claims 27-28).

Nonetheless Keller teaches other medicaments may be employed (see abstract and col. 7, lines 10-12).

Hill teaches low foaming toothpaste with soft abrasives that is employed with a ribbed and grooved bristled tooth brush (as required by instant claim 26a), wherein the toothbrush includes 3-5 ribs and grooves (as it relates to claims 29-33; see abstract, Figs 1-4b and col. 6, lines 47 and 58 for the abrasives) and wherein the toothpaste comprises non-ionic surfactants and polydimethylsiloxanes, (see col. 7, lines 45-47 and col. 11, line 33, as required by instant claims 34-36). Because toothpaste would be used on a toothbrush, it would be obvious that brushing of the supragingival occurs. It should be noted that with regards to the limitation of “gingival detachment of at least 3 mm”, Keller teaches gingival detachment.

However, Hill fails to teach the specific therapeutic agents such as NSAIDs and dental floss.

Aberg et al teach reducing dental caries/cavities by administering toothpaste with a medicament such as NSAIDs for treating periodontal disease, (see abstract and col. 6, lines 49-58; as required by instant claims 23-25). Because toothpaste would be used on a toothbrush, it would be obvious that brushing of the supragingival occurs.

However Aberg fails to teach using ribbed and grooved bristled tooth brushes.

One of ordinary skill in the art would have been motivated to expand the teaching of Keller to remove biofilm removal with a tooth brush and floss by substituting the tooth brush of Keller with Hill's, since Hill specifically teach use of ribbed grooved bristle tooth brushes to brush the supragingival tooth surface of the tooth, wherein it is well known

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that brushing with toothpaste removes biofilm. Employing the toothbrush and the soft abrasive toothpaste of Hill will intrinsically result in the abrasives physically being worked into the supra and subgingival pockets of the patients mouth suffering from periodontal disease.

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Keller and Hill with Aberg et al and add a NSAID to the toothpaste or dental floss for the treatment of periodontal disease because Aberg teaches periodontal disease relates to a condition in which the gingival and the alveolar bone become detached if periodontal disease is not treated, and the bacteria that causes the periodontal disease can gain access to the blood stream and cause vascular disease. Therefore, one of ordinary skill in the art would have been motivated to add Aberg's NSAID to toothpaste for brushing or add NSAID to dental floss for flossing and remove biofilm in pockets of the tooth of the patient suffering from periodontal disease because Keller teaches that therapeutic agents maybe added to such formulation with a reasonable expectation of success.

8. No claim is allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Grady (Grady New York Times 1998)

- diseases of the mouth are linked to heart disease (see entire publication).



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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./  
Examiner, Art Unit 1618  
8/6/09

/Robert C. Hayes/  
Primary Examiner, Art Unit 1649